

MATERIAL FOR FABRICATION OF ARTIFICIAL INTRAOCULAR LENSES AND HARD CONTACT LENSES

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to improvements in ophthalmology and more particularly to artificial intraocular lenses (pseudophakoi) used for the correction of aphakia and re-establishment of binocularity in aphakia and to the fabrication of hard contact lenses arranged to be placed over the cornea. It further relates to improved methods of fabricating PMMA for subsequent fabrication of such lenses.

2. Discussion of the Prior Art

Well-fixed and well-centered intraocular lens implants are used to produce stable retinal images and re-establish binocularity in causes of aphakia. Many techniques of lens implantation exist including suturing to the ciliary muscle as disclosed in U.S. Pat. No. 3,711,870, iris diaphragm fixation as discussed in U.S. Pat. No. 3,673,616 and combinations of anterior and posterior iris clips as disclosed in U.S. Pat. Nos. 3,925,825 and 3,922,728. The lenses used in these various techniques are preferably fabricated of PMMA because of the easy machinability and proven physiological compatibility with the eye. Other materials which have been suggested include quartz and ophthalmic glass. Polymethylmethacrylate resins such as those available under the tradenames "LUCITE" and "PLEXIGLAS" and biologically neutral chemically pure polymeric materials in addition to the PMMA mentioned above but which are proven biologically inert, i.e., not susceptible to being absorbed by body fluids and capable of being well tolerated by the human body when implanted, have likewise been used. Comparable materials have been suggested for use in fabrication of hard contact lenses. "Hard" contact lenses are hereinafter distinguished from the so-called soft contact lenses which are characterized by hydration for usage. Generally, so-called soft contact lens compositions contain from 35 to 80 percent by weight of water when they are swelled to final dimension for usage. Hard contact lenses (and the hard polymerized precursor buttons from which soft contact lenses are made) are amenable to known machining, cutting and polishing techniques as described for example in U.S. Pat. Nos. 2,330,837, 3,227,507, 3,700,761 and others.

Machinability, color uniformity, and optical quality are properties to be desired in materials from which intraocular implant lenses and hard contact lenses are to be made. Especially in the case of hard contact lenses where it is desired to make lenses as thin as possible, it is desired that machinability be superior. Yet further, after machining, it is desired that the thin or ultra thin lenses be characterized by freedom from strain and warpage. Freedom from warpage is necessary to maintain the relative fit of the lens to the cornea and the net prescription which is ground or otherwise formed into the lens. In particular, it is desirable to make hard contact lenses as thin as possible to make them more comfortable to the wearer. To the best of our knowledge and belief, thin contact lenses to date have been on the order 0.12 millimeters thick on a commercial scale. Using concepts of the present invention, it is possible to make ultra thin hard contact lenses; that is, lenses on the

order of 0.07 millimeters thick, depending in part, on the power of the lens.

After fabrication of the lenses, it is desirable they be free of strain. Strain is a phenomenon which can normally only be seen with polarized light. The strain appears as mottled colors or in maltese cross-like patterns. Such undesirable strain patterns can also be seen in some situations when being worn, for example, when worn in association with polarized sunglasses. In the case of both intraocular implants and hard contact lenses, it is desired that the rod from which buttons are cut (and the buttons themselves from which the lenses are machined) be capable of or exhibit substantially uniform coloration from one edge to the other. In this regard, it is desired that the rods from which the buttons are made be of substantially uniform dimension and roundedness.

Prior methods of preparing rods from which precursor contact lens and intraocular lens buttons were made have had a number of difficulties. One method which has proven itself highly successful for the fabrication of soft contact lenses is disclosed and claimed in our co-pending application entitled "Fabrication of Soft Contact Lens and Composition Therefor", Ser. No. 526,022 filed Nov. 21, 1974. That method included the usage of a polytetrafluoroethylene tube having positioned therein a sheet of polyethylene terephthalate film in spiral form. Polymer was cast within the film spiral. Monomer material leaked around the wrap and had other undesirable characteristics when attempts were made to cast PMMA in a comparable fashion. In attempting to overcome some of the difficulties encountered in trying to adopt the method of application Ser. No. 526,022, we tried glass tubes. The tubes were sealed from the atmosphere by appropriate plugs and nonoxidizing atmospheres. In one instance, we used a nitrogen filled balloon about the open end of the tube into which the monomer was cast. While the rods recovered from such a glass casting system were more uniform in composition, they were not more uniform in geometry, quite surprisingly. The rods recovered were noncircular in that they had flat areas along the length of the rod. Also, the glass tubes seemed to become more fragile with repeated use. While not able to fully understand the phenomenon by which this increase in fragility occurs, we postulate a fatigue was induced in the glass. This may have been due to leaching of minor constituents from the glass, or an accumulation of scratches during handling and cleaning.

In any event, we next tried metal tubes of stainless steel and aluminum. We selected these metal tubes because of the desirability of controlling the exothermic reaction which occurs when the PMMA is polymerizing. These metal tubes were also not entirely satisfactory. Among other things, noncircular flat areas formed on the cast rods and there was much sticking. Next, we tried tubes of Teflon. Teflon is the trademark of the DuPont Company for a waxy opaque material called polytetrafluoroethylene. This material has been used, for example, on cooking utensils and in many industrial applications to prevent sticking. The combination of teflon tubes within a copper or aluminum stiffener proved successful in accomplishing the objects of the invention; that is, the reproducible manufacture of a PMMA hard contact lens and intraocular lens precursor material characterized by good machinability, color uniformity and optical quality. Certain Teflon coatings on metal tubing has also accomplished this same end.